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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,434	02/24/2006	Tzung-Horng Yang	037003-0313985	7954

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
03/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket_ip@pillsburylaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/518,434	YANG ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,22-82 and 102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,22-82 and 102* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a concentrated antibody solution consisting essentially of an aqueous solution of antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM. In view of this Lam et al (6,171,586 B1, issued 1/9/2001, IDS reference AR filed 7/17/06) reads on the claim. Lam et al teach an antibody composition comprising an anti-CD20 antibody in 25 mM histidine at different pH's (e.g., see Fig. 4 and legend at col. 4). Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1 and 102, drawn to a concentrated antibody composition consisting essentially of an aqueous solution of antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM and a kit comprising such.

Group II, claims 23-41, 43-61 and 63-81, drawn to a method of producing a concentrated anti-CD80 or anti-CD80 IDEC-114 antibody preparation comprising providing an initial antibody preparation consisting essentially of an aqueous solution of anti-CD80 or anti-CD80 IDEC-114 antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM, subjecting the initial anti-CD80 or anti-CD80 IDEC-114 antibody preparation to membrane filtration that removes water and buffer but not antibodies from the anti-CD80 or anti-CD80 IDEC-114

antibody preparation, thereby producing an anti-CD80 or anti-CD80 IDEC-114 antibody preparation having a higher concentration of anti-CD80 or anti-CD80 IDEC-114 antibodies than the initial antibody preparation.

Group III, claims 23-41, 43-61 and 63-81, drawn to a method of producing a concentrated anti-gp39 or anti-gp39 IDEC-131 antibody preparation comprising providing an initial antibody preparation consisting essentially of an aqueous solution of anti-gp39 or anti-gp39 IDEC-131 antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM, subjecting the initial anti-gp39 or anti-gp39 IDEC-131 antibody preparation to membrane filtration that removes water and buffer but not antibodies from the anti-gp39 or anti-gp39 IDEC-131 antibody preparation, thereby producing an anti-gp39 or anti-gp39 IDEC-131 antibody preparation having a higher concentration of anti-gp39 or anti-gp39 IDEC-131 antibodies than the initial antibody preparation.

Group IV, claims 23-41, 43-61 and 63-81, drawn to a method of producing a concentrated anti-CD4 or anti-CD4 IDEC-151 antibody preparation comprising providing an initial antibody preparation consisting essentially of an aqueous solution of anti-CD4 or anti-CD4 IDEC-151 antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM, subjecting the initial anti-CD4 or anti-CD4 IDEC-151 antibody preparation to membrane filtration that removes water and buffer but not antibodies from the anti-CD4 or anti-CD4 IDEC-151 antibody preparation, thereby producing an anti-CD4 or anti-CD4 IDEC-151 antibody preparation having a higher concentration of anti- anti-CD4 or anti-CD4 IDEC-151 antibodies than the initial antibody preparation.

Group V, claims 23-41, 43-61 and 63-81, drawn to a method of producing a concentrated anti-CD23 or anti-CD23 IDEC-152 antibody preparation comprising providing an initial antibody preparation consisting essentially of an aqueous solution of anti-CD23 or anti-CD23 IDEC-152 antibodies and histidine or acetate buffer at a

concentration in the range of from about 2 mM to about 48 mM, subjecting the initial anti-CD23 or anti-CD23 IDEC-152 antibody preparation to membrane filtration that removes water and buffer but not antibodies from the anti-CD23 or anti-CD23 IDEC-152 antibody preparation, thereby producing an anti-CD23 or anti-CD23 IDEC-152 antibody preparation having a higher concentration of anti-CD23 or anti-CD23 IDEC-152 antibodies than the initial antibody preparation.

Group VI, claims 23-41, 43-61 and 63-81, drawn to a method of producing a concentrated anti-CD20 or rituximab antibody preparation comprising providing an initial antibody preparation consisting essentially of an aqueous solution of anti-CD20 or rituximab antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM, subjecting the initial anti-CD20 or rituximab preparation to membrane filtration that removes water and buffer but not antibodies from the anti-CD20 or rituximab preparation, thereby producing an anti-CD20 or rituximab preparation having a higher concentration of anti-CD20 or rituximab than the initial antibody preparation.

Group VII, claim 82, drawn to a method of therapy comprising administering a pharmaceutical composition comprising antibody composition consisting essentially of an aqueous solution of antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM and a pharmaceutically acceptable carrier.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Lam et al the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Claims 22, 42 and 62 link inventions II-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 22, 42 and 62. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The methods of Inventions II-VII differ in the method objectives, method steps and parameters and in the reagents used. Invention II-VI recite methods of producing a concentrated antibody preparations comprising providing an initial antibody preparation consisting essentially of an aqueous solution of antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM, subjecting the initial antibody preparations to membrane filtration that removes water and buffer but not antibodies from the antibody preparation, thereby producing an antibody preparation having a higher concentration of antibodies than the initial antibody preparation, wherein Groups II-VI require an anti-CD80 antibody, an antigp39 antibody, an anti-CD4 antibody, an anti-CD23 antibody and an anti-CD20 antibody, respectively; the invention of Group VII recites a method of therapy comprising administering a pharmaceutical composition comprising antibody composition consisting essentially of

an aqueous solution of antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM and a pharmaceutically acceptable carrier. The inventions of Groups II-VI are directed to methods that recite structurally and functionally distinct elements and are not required one for the other. The invention of Group II requires an anti-CD80 antibody, which is not required by any of the other groups. Similarly, the inventions of Groups III-VI are directed to methods that recite structurally and functionally distinct elements (i.e., an antigp39 antibody, an anti-CD4 antibody, an anti-CD23 antibody and an anti-CD20 antibody, respectively) and are not required one for the other. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, inventions II-VII are separate and distinct in having different method objectives, method steps, parameters, reagents used and different endpoints and are patentably distinct.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the concentrated antibody composition of Group I can be used in a materially different method such as to immunopurify the antigen in addition to the materially different therapeutic method of Group VII.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example,

searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643